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| 10/587,534 | 09/12/2007 | Norman Booth | 3485-P10380US (69105USP00) | 9688 |
| 24247 | 7590 | 03/14/2011 | EXAMINER | |
| TRASKBRITT, P.C. P.O. BOX 2550 SALT LAKE CITY, UT 84110 | | | WILSON, LARRY ROSS | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3767 | |
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| | | | 03/14/2011 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOMail@traskbritt.com

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/587,534 | Applicant(s) BOOTH, NORMAN | |
| | Examiner LARRY R. WILSON | Art Unit 3767 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 20 January 2011 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,071,274 to Russell B. Thompson et al. (Thompson) in view of U.S. Patent Application 2001/0007070 to Mark T. Stewart et al. (Stewart).

In regards to claim 1, Thompson teaches a catheter assembly, including:

at least one introducer having a longitudinal axis (Fig. 14, #102),

the at least one introducer defining at least one passage (col. 13, lines 45-47, Fig. 14, 15A),

an elongate tubular member (Fig. 1, #12, 100) slidably received within the at least one passage of the at least one introducer (col. 14, lines 15-16),

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the tubular member having a proximal end (Fig. 1, #14) and a distal end (Fig. 1, #16) and at least one lumen extending between the proximal end and the distal end (col. 13, lines 38-41), and

an elongate, shape-imparting element received in the at least one lumen of the tubular member (Fig. 14, #22) to extend from the proximal end of the tubular member (col. 8, lines 45-48; col. 14, lines 7-9 – the shape-imparting element forms the core of the tubular member) and the introducer (Fig. 14, #22, 64) and through the distal end of the tubular member (col. 14, lines 7-9), the shape-imparting element imparting a predetermined shape to the distal end of the tubular member when the distal end of the tubular member is extended beyond a distal end of the introducer (col. 14, lines 21-24), a distal end of the shape-imparting element extending beyond the distal end of the tubular member (col. 14, lines 7-10) and being anchored proximally a distal end of the introducer (Fig. 15A, #143) at a location external of the introducer (Fig. 15A, #143).

But Thompson does not teach the elongate shape-imparting element is one-piece, the predetermined shape including a formation in a plane substantially orthogonal to the longitudinal axis of the introducer,...wherein, due, at least in part, to the anchoring of the distal end of the shape-imparting element to the introducer, the formation is adjusted in the plane substantially orthogonal to the longitudinal axis of the introducer in terms of an inner area of the predetermined shape in the plane substantially orthogonal to the longitudinal axis of the introducer, when torsion is applied to the shape-imparting element.

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Stewart teaches the predetermined shape including a formation in a plane substantially orthogonal to the longitudinal axis of the introducer (para. 98),...wherein, due, at least in part, to the anchoring of the distal end of the shape-imparting element to the introducer (Thompson Fig. 15A, #143), the formation is adjusted in the plane substantially orthogonal to the longitudinal axis of the introducer in terms of an inner area of the predetermined shape in the plane substantially orthogonal to the longitudinal axis of the introducer, when torsion is applied to the shape-imparting element (Thompson col. 10, lines 25-31).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the cranked arm and spiral shape of Stewart in the ablation catheter of Thompson in order to create a continuous closed lesion ablation about the ostium isolating the pulmonary vein from the left atrium to treat atrial fibrillation (para. 12, 14) as taught by Stewart.

Furthermore, one of ordinary skill in the art at the time the invention was made would have found it an obvious design choice to use a one-piece shape-imparting element in order to simplify the construction and assembly, and prevent accidental disconnection of joints. See MPEP 2144.04.

Thompson teaches an anchor point for the shape-imparting element and that rotation would adjust the shape of the loop generally orthogonally, and Stewart teaches a transverse loop. One of ordinary skill would understand that if the loop were formed in a predetermined shape as taught by Stewart applying torsional forces would change the size of the loop because the loop is in the plane of rotation caused by the torsional forces, and

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the anchor of the shape imparting element as taught by Thompson would limit flipping or changes in orientation of the loop, thus the device of Thompson, as modified by Stewart, would allow the change in diameter of the loop as required by claims 1 and 16.

In regards to claims 2-15, Thompson teaches the assembly of claim 1 and further discloses:

Claim 2: in which a proximal end of the shape-imparting element is connectable to a control mechanism (Fig. 1, #36) which, in use, applies torsion to the shape-imparting element to effect adjustment of the predetermined shape of the distal end of the tubular member (col. 10, lines 25-31 – by rotating the catheter, which is connected to the tubular member 20, 100, the shape imparting spline also rotates changing the shape since the spline is a nitinol shape-memory wire);

Claim 3: in which the predetermined shape imparted to the distal end of the tubular member is a loop formation (Fig. 15A);

Claim 4: the tubular member forms a cranked arm (Stewart Fig. 1A, #36) when it is extended from its introducer (para. 97), the cranked arm being arranged transversely with respect to a longitudinal axis of the introducer and the cranked arm leading into a spiral shape forming the loop formation (para. 98);

Claim 5: the spiral shape circumscribes at least 360° (Stewart Fig. 8);

Claim 6: the spiral shape circumscribes about 540° (Stewart Fig. 8);

Claim 7: the cranked arm extends from the end of the introducer at an included angle of about, or exceeding, 90°... (Stewart para. 98);

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Claim 8: in which the assembly includes at least two introducers (Fig. 32, #12, 232), each introducer having a tubular member associated with it (Fig. 34, #220 – the tubular members are slidable relative to the first introducer 12, which is within sheath 232, therefore each introducer has a tubular member associated with it, directly or via the first introducer);

Claim 9: in which a first introducer (Fig. 32, #12) is received within a passage of a second introducer (Fig. 32, #232), a second tubular member (Fig. 34, #220), associated with the second introducer (Fig. 34, #220 – the tubular members are slidable relative to the first introducer 12, which is within sheath 232, therefore each introducer has a tubular member associated with it), being slidably received within a passage of the second introducer (col. 19, lines 56-62);

Claim 10: in which the second tubular member (Fig. 34, #220) is carried on a shape-imparting element received within a lumen of the second tubular member (Fig. 34, #212, 214, 216) so that the second tubular member is able to be formed into a second predetermined shape when the second tubular member is extended from the second introducer (col. 19, lines 51-55);

Claim 11: in which the shape-imparting element associated with the second tubular member extends beyond a distal end of the second tubular member (Fig. 34);

Claim 12: in which a distal end of the second shape-imparting element is anchored distally with respect to the distal end of the second tubular member but proximally with respect to the distal end of the first introducer (col. 19, lines 42-48 – one region

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is anchored 211 to the distal end 16 of first introducer 12, the other region 213 slidable);

Claim 13: in which an anchor point of the first shape-imparting element is in register with an anchor point of the second shape- imparting element (col. 19, lines 42-48 – all loops are anchored to the catheter distal end);

Claim 14: in which both anchor points are arranged on the first introducer (col. 19, lines 42-48 – all loops are anchored to the catheter distal end);

Claim 15: in which each shape-imparting element is in the form of a shape memory alloy wire (col. 8, lines 49-51).

In regards to claim 16, Thompson teaches a catheter assembly which includes:
at least one introducer (Fig. 14, #102),
the at least one introducer defining a passage (col. 13, lines 45-47, Fig. 14, 15A),
an elongate, tubular member (Fig. 1, #12, 100) slidably received within the passage of the at least one introducer (col. 14, lines 15-16),
the tubular member having a proximal end (Fig. 1, #14) and a distal end (Fig. 1, #16) and a lumen extending between the proximal end and the distal end (col. 13, lines 38-41), and an elongate, shape-imparting element received in the lumen of the tubular member (Fig. 14, #22), to extend from the proximal end of the tubular member (col. 8, lines 45-48; col. 14, lines 7-9 – the shape-imparting element forms the core of the tubular member) and the introducer (Fig. 14, #22, 64) and through the distal end of the tubular member (col. 14, lines 7-9), a distal end of the shape-imparting element extending beyond a distal end

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of the tubular member (col. 14, lines 7-10) and being anchored proximally a distal end of the introducer (Fig. 15A, #143) and at a location external of the introducer (Fig. 15A, #143), the arrangement being such that, when a distal portion of the tubular member is extended beyond the distal end of the introducer, the shape-impacting element imparts a predetermined shape to the distal portion of the tubular member (col. 14, lines 21-24).

But Thompson does not teach the elongate shape-impacting element is one-piece, the predetermined shape comprising a cranked arm portion extending transversely relative to a longitudinal axis of the introducer, and a loop formation supported on the arm portion so that torsion imparted to a proximal end of the shape-impacting element causes rotation of the arm portion about the longitudinal axis of the introducer to effect adjustment of a diameter of the loop formation of the distal portion of the tubular member.

Stewart teaches the predetermined shape comprising a cranked arm portion (Fig. 1A, #36) extending transversely relative to a longitudinal axis of the introducer (para. 98), and a loop formation supported on the arm portion (para. 98) the loop formation extending about the longitudinal axis of the introducer (para. 98), wherein due to the anchoring of the distal end of the shape-impacting element to the introducer (Thompson Fig. 15A, #143), applying torsion to the shape-impacting element effects adjustment of a diameter of the loop formation of the distal portion of the tubular member (Thompson col. 10, lines 25-31).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the cranked arm and spiral shape of Stewart in the ablation catheter of Thompson in order to create a continuous closed lesion ablation about the

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ostium isolating the pulmonary vein from the left atrium to treat atrial fibrillation (para. 12, 14) as taught by Stewart.

Furthermore, one of ordinary skill in the art at the time the invention was made would have found it an obvious design choice to use a one-piece shape-imparting element in order to simplify the construction and assembly, and prevent accidental disconnection of joints. See MPEP 2144.04.

Thompson teaches an anchor point for the shape-imparting element and that rotation would adjust the shape of the loop generally orthogonally, and Stewart teaches a transverse loop. One of ordinary skill would understand that if the loop were formed in a predetermined shape as taught by Stewart applying torsion would change the size of the loop because the loop is in the plane of rotation caused by torsion, and the anchor of the shape imparting element as taught by Thompson would limit flipping or changes in orientation of the loop, thus the device of Thompson, as modified by Stewart, would allow the change in diameter of the loop under torsion as required by claims 1 and 16.

Response to Amendment

4. The amendment to claims 1 and 16 in the response filed on 20 January 2011 is acknowledged.

Response to Arguments

5. Applicant's arguments with respect to claims 1-16 have been considered but are moot in view of the new ground(s) of rejection.

6. The new grounds of rejection were necessitated by the amendment to claims 1 and 16.

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Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LARRY R. WILSON whose telephone number is (571)270-5899. The examiner can normally be reached on Monday-Thursday 7:00 AM - 5:30 PM (EST).

8. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LARRY R WILSON/
Examiner, Art Unit 3767

/Theodore J Stigell/
Primary Examiner, Art Unit 3763